K132255

Section 5

Traditional 510(k) Summary

This summary of the Traditional 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR 807 .92.

Applicant's Name and Address

OCT 24 2013

Ultradent Products, Inc.
505 West 10200 South
South Jordan, UT 84095

Contact Person:	Diane Rogers
Title:	Manager of Regulatory and Global Affairs
Telephone:	(800) 552-5512 x4491, (801) 553-4491
FAX:	(801) 553-4609
Date Summary Prepared:	July 18, 2013

Name of the Device

Trade Name:	UltraCem™
Common Name:	Dental Cement
Device Classification:	Class II
Classification Product Code:	EMA

Legally Marketed Predicate Devices to Which Equivalence is Claimed

The predicate device is: K111855 Hy-Bond Resiglass by Shofu dental of San Marcos, CA 92078

UltraCem™ is very similar to our predicate device in that both devices are intended to be used as dental cements.

Indications for Use: UltraCem™ is indicated for cementation of indirect restorations (including inlays, onlays, crowns and bridges) made of metal, porcelain fused to metal, zirconia, and resin to natural teeth. This product is also intended for cementation of orthodontic bands to natural teeth.

Product Description: UltraCem™ is a chemical cure, resin reinforced (modified) glass ionomer cement.

Technological characteristics

UltraCem™		UltraCem™ is indicated for cementation of indirect restorations (including inlays, onlays, crowns and bridges) made of metal, porcelain fused to metal, zirconia, and resin to natural teeth. This product is also intended for cementation of orthodontic bands to natural teeth.
Hy-Bond Resiglass	111855	Hy-Bond Resiglass is intended for cementation of restorations (including inlay, crown and bridge) made of metal, ceramics (porcelain) and resin to natural teeth. This product is also intended for cementation of orthodontic appliances (metal bracket, ceramic bracket, etc) to natural teeth.
Characteristics	Glass ionomer cement	Glass ionomer cement
Human Factors	Syringe delivery or brush and bottle	Brush and bottle
Biocompatibility	Not performed as the formula is the same as our predicate and then the product is placed in our own syringe delivery system, or used in bottles.	ISO 10993 Cytotoxicity Sensitization Irritation Genotoxicity

UltraCem™ is supplied in a pre-mixed syringe for easy delivery and no waste, and also in two part bottles to be mixed with application brushes then directly applied to surfaces.

Hy-Bond Resiglass is supplied in two part bottles to be mixed with application brushes then directly applied to surfaces.

The patient population is intended for all ages that need a restoration or repair as prescribed by a dentist. UltraCem™ is a chemical cure, resin reinforced (modified) glass ionomer cement.

Brief Description of Testing Performed

The following bench tests were conducted during the R & D phase on UltraCem™ and compared to K111855 Hy-Bond Resiglass. Final test results are in Section 18 "Bench Testing".

Shear bond: This *in-vitro* test determines how well the material enhances the bonding to various surfaces compared to both the Hy-Bond system and the UltraCem™ system. UltraCem™ is comparable to Hy-Bond which is currently on the market and is well-received.

Working-Setting Time: The working time was determined to be when the product began to display gel-like polymerization properties. The setting time was determined to be the time when the product was polymerized to the point when the mass could be moved as a whole.

Film Thickness: A micrometer was zeroed on two glass cover slips. A small drop of product was placed between the cover slips, which were then placed underneath a load for several seconds. The thickness was measured in microns and recorded.

Flexural Strength: Samples were prepared with each product and allowed to cure, then stored in 40° water for 24 hours. The samples were tested and the strengths were recorded.

Radiopacity: Specimens were allowed to cure then placed under an X-Ray machine and compared to determine how well the products can be viewed in an X-Ray.

Clinical Summary

A complete Clinical Summary of UltraCem™ is included in Section 20. We conducted a literature study to show substantial equivalence in safety and effectiveness of this product. The product can be used on any age patient when treatment is prescribed by a dentist. The device has the same technological characteristics compared to K111855 Hy-Bond Resiglass by Shofu dental of San Marcos, CA 92078.
Hy-Bond Resiglass has been widely used by numerous dentists in the dental industry.

The intended purpose of UltraCem™ has been demonstrated by a combination of in-house testing and side-by-side comparisons to a predicate device currently on the market. Results of our bench testing indicates that UltraCem™ is substantially equivalent to the predicate device currently on the market. (Test results are in Section 18 Bench Testing).

Summary
Risk/Benefit Review

Considering the safe history of our predicate, K111855 Hy-Bond Resiglass by Shofu dental of San Marcos, CA 92078 UltraCem™ is substantially equivalent to our predicate device. Our research indicates that our predicate has been used by many dentists and large group practices in the United States and purchased by a large number of international distributors. To date, there have been no reported complaints of local or systemic adverse effects associated with the use of the predicate product.

UltraCem™ was not tested for biocompatibility as our predicate (K111855) has the same exact formula and ingredients and their product was tested in Cytotoxicity, Sensitization, Irritation and Genotoxicity tests according to ISO 10993-1.

In conclusion, UltraCem™ has been designed and manufactured with the intended use and claims for the product in mind. Scientific literature, etc. has been collected and evaluated and determined to be substantially equivalent in safety and effectiveness of similar products used for the same indication. Following the clinical review as documented above, Ultradent Products, Inc. deems that when this device is used under the conditions and for the purposes intended, it will not compromise the clinical condition and the association with its use constitutes acceptable risks when weighed against the benefits to the patient. Therefore, the product is substantially equivalent and may be released to the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 24, 2013

Ultradent Products, Incorporated
C/O Ms. Diane Rogers
Regulatory and Global Affairs Manager
505 West 10200 South
South Jordan, Utah 84095

Re: K132255
Trade/Device Name: UltraCem™
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: II
Product Codes: EMA, DYH
Dated: August 8, 2013
Received: August 9, 2013

Dear Ms. Rogers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820): and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K132255

Statement of Indications for Use

510(k) Number (if known): _____

Device Name: UltraCem™

Indications for Use:

UltraCem™ is indicated for cementation of indirect restorations (including inlays, onlays, crowns and bridges) made of metal, porcelain fused to metal, zirconia, and resin to natural teeth. This product is also intended for cementation of orthodontic bands to natural teeth.

Prescription Use _X_ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner -S
2013.10.24
11:07:08 -04'00'

(Posted November 13, 2003)